

UC San Diego

UC San Diego Previously Published Works

Title

Sensing and actuation technologies for smart socket prostheses.

Permalink

<https://escholarship.org/uc/item/3hn1p5df>

Journal

Biomedical engineering letters, 10(1)

ISSN

2093-9868

Authors

Gupta, Sumit
Loh, Kenneth J
Pedtke, Andrew

Publication Date

2020-02-01

DOI

10.1007/s13534-019-00137-5

Peer reviewed

Sensing and Actuation Technologies for Smart Socket Prostheses

Sumit Gupta¹, Kenneth J. Loh^{1,*}, Andrew Pedtke²

¹Department of Structural Engineering, University of California-San Diego, La Jolla, CA,
92093-0085, USA

²LIM Innovations, San Francisco, CA, USA

*Corresponding author e-mail: kenloh@ucsd.edu

Abstract

The socket is the most critical part of every lower-limb prosthetic system, since it serves as the interfacial component that connects the residual limb with the artificial system. However, many amputees abandon their socket prostheses due to the high-level of discomfort caused by the poor interaction between the socket and residual limb. In general, socket prosthesis performance is determined by three main factors, namely, residual limb-socket interfacial stress, volume fluctuation of the residual limb, and temperature. This review paper summarizes the various sensing and actuation solutions that have been proposed for improving socket performance and for realizing next-generation socket prostheses. The working principles of different sensors and how they have been tested or used for monitoring the socket interface are discussed. Furthermore, various actuation methods that have been proposed for actively modifying and improving the socket interface are also reviewed. Through the continued development and integration of these sensing and actuation technologies, the long-term vision is to realize *smart socket* prostheses. Such smart socket systems will not only function as a socket prosthesis but will also be able to sense parameters that cause amputee discomfort and self-adjust to optimize its fit, function, and performance.

Keywords

Actuation, interfacial stress, lower-limb amputees, sensors, self-adjust, socket prosthesis, smart socket, temperature, volume fluctuation.

1 Introduction

Limb amputation and the resulting physical disability adversely impacts the quality of life of amputees. According to a report published by the World Health Organization, there are ~ 40 million amputees worldwide. In the U.S., ~ 185,000 amputations are performed each year, and nearly 2 million people suffer from amputations [1]. Overall, ~ 54% of all amputations are due to vascular diseases, with the remaining ~ 46% caused by severe trauma and cancers [2]. These statistics have increased due to recent military conflicts. For example, the number of combat-related amputations increased from ~ 960 to 1200 between 2010 and 2012 [3]. While amputations need to be performed as a medical necessity, the main concern is to provide a better quality of life for amputees after limb loss.

Prostheses serve to restore the lost functionalities of amputees. It has been shown that consistent prosthetic use reduces secondary health issues and provides a larger degree of mobility and functional independence for those with amputation [4]. Increased prosthetic usage correlates with higher levels of employment [4], increased quality of life [5], decreased phantom limb pain, and lower levels of general psychiatric symptoms.

In the case of lower limb amputations, the prosthetic system functions as the crucial component that transfers loads from the upper body through the residual limb to the artificial limb. In particular, socket prostheses consist of a socket, a shank, the ankle, and foot, and its purpose is to replace the amputated limb. The socket is responsible for coupling the residual limb with the rest of the components of the prosthesis. Traditionally, the socket is a rigid or semi-rigid

component that is purposefully designed to conform to the shape of each amputee's residual limb. Yet, socket gold standards are an undefined topic in the field of prosthetics. Born out of a custom fabrication process that entails plaster casting followed by lamination, the socket continues to remain a one-off device. Although there have been advances in computer-aided design and manufacturing (CAD-CAM) technology or 3D printing, these are primarily manufacturing solutions. The end result, being a rigid device that gives a snapshot window of limb volume, size, and shape is still the standard solution. Unfortunately, the prosthetic socket and methods have seen little advancement in the past 50 years.

In fact, less than 50% of amputees wear their prosthesis regularly [6, 7], and the primary cause of prosthetic abandonment is due to socket discomfort [8] and fitment [9]. Prosthetic abandonment is especially prevalent among users with an above the knee amputation with a short femur, resulting in psychological problems, reduced quality of life, and lack of community engagement [10]. Chamlian *et al.* [11] observed elevated abandonment rates (62.5%) and daily usage decrements (31-85%) following discharge from rehabilitation. The inability for conventional sockets to respond to the daily needs of amputees leads to short-term and long-term consequences. The majority of users require multiple replacement sockets per year, costing upwards of \$30,000 [12]. In severe cases, users are forced to undergo revisions of their amputation. This cyclic process creates not only financial burdens to amputees and the healthcare system but also reflects the fragmentation of the care continuum and the lack of coordinated efforts to ensure appropriate access to medical care.

To ensure proper fitment of the socket, the three main factors that should be considered are the pressure distribution at the socket-residual limb interface, local body (limb) temperature, and volume fluctuations of the residual limb. Nonuniform contact pressure can cause hotspots that result in pain and skin-related issues. Blood perfusion and a change in metabolic rate can result in an increased temperature of the residual limb to cause sweating. In this case, excessive sweating can cause skin irritation and maceration, which can worsen and result in skin breakdown and **acute infection**. In unequal interfacial stress- and temperature-related issues, a change in the residual limb's volume can result in excessive displacement (*i.e.*, in the case of limb shrinkage) or increased shear forces between the residual limb and socket (*i.e.*, in the case of limb expansion). **Besides, the gait pattern of amputees can change due to improper fitment of the socket. Abnormalities in the gait patterns could result in walking instability [13] and an increase in energy consumption as a result of compensatory muscle activity [14], to name a few.**

Therefore, the purpose of this review paper, which differentiates itself from other review articles on prostheses [15-18], is to summarize the different sensing technologies employed for measuring and modifying the three leading factors that govern socket prosthesis fitment: contact pressure distribution, local temperature, and volume fluctuations. The next three sections each begin with a description of technologies that have been used for measuring the specific physical phenomenon of interest and their associated challenges. Furthermore, to capture other issues that drive the development of next-generation smart socket prostheses, **various sensing modalities for monitoring gait and infection are also briefly summarized**. Then, new designs or proposed changes to the socket prosthesis that mitigate these effects are discussed. It should be mentioned that this paper is not meant to be an exhaustive review of all the technologies developed and presented to date. Instead, only certain technologies are highlighted to showcase the breadth and opportunities of this field. Finally, the paper concludes with a discussion of the vision for realizing next-generation smart socket prostheses.

2 Interfacial Pressure Distribution

One of the most critical factors in determining fitment and comfort depends on the distribution of contact pressure at the interface between the residual limb and socket prosthesis [19]. Pressure hotspots resulting from nonuniform pressure distributions acting on the residual limb for long periods of time can cause pressure ulcers, vascular occlusions, and skin irritations, to name a few [20]. These problems often hinder blood flow in the residual limb, which can lead to an increase in temperature, perspiration, and dermatitis [21-23]. If these issues are not addressed early, skin problems and tissue infection can follow. Furthermore, these issues can escalate, and the patient may need to undergo re-amputation [24]. Hence, pressure monitoring at the residual limb-sockets interface needs to be the first and foremost step taken to reduce discomfort and skin-related issues at the limb-prosthesis interface [25].

Although the relationship between the level of discomfort and interfacial pressure is highly subjective and depends on the condition of the muscles in the residual limb [26], Ogawa *et al.* [27] was able to quantify the pain-raising pressure threshold for the fossa popliteal and patellar tendon as ~ 50 kPa and ~ 120 kPa, respectively. However, it was found that the sensitivity of pain depends on the location of the residual limb. For example, pain sensitivity is relatively low near the front side of the thigh and higher in the rear. Kahle *et al.* [28] reported that a nondisabled person experiences negligible pressure on the ischial tuberosity while standing, while pressure can increase to as high as 300 mmHg during normal sitting. This is significant enough to cause tissue damage for sensory- and mobility-impaired individuals. Since it is not possible to define a single value of pain-causing pressure threshold, the first step to solve this problem would be to quantify the stress distribution at the residual limb-socket interface. In general, four main types of sensors are used for pressure measurements in the socket, which are: (1) strain gages (2) piezoresistive, (3) capacitive, and (4) optical sensors. Each type of these sensors, their integration in socket prostheses, and limitations are described in detail in the following subsections.

2.1 Strain gages

Strain gages are patches of patterned metal foil on a flexible plastic backing that exhibit a change in their resistance in response to applied strains [29]. Strain gages are regarded as the most well-known and widely used strain sensor because of their high accuracy, resolution, and reliability [30]. The use of strain gages in the lower limb prosthesis first began in the 1960s [31]. Strain gages are mainly used as a diaphragm deflection transducers inserted in the socket to measure normal stress [27] or as a piston-type transducer mounted on the socket wall to measure both normal and shear stresses [17].

The Kulite sensor is the most commonly used diaphragm deflection transducer for measuring stress in the socket prosthesis [32-39]. Here, 2- to 3-mm-diameter and 0.8-mm-thick sensing elements are tethered to four 0- to 5-mm-thick conductor ribbon cables on its bottom to achieve electrical connections. Kulite sensors are monolithic and employed on a silicone diaphragm in a Wheatstone bridge configuration for strain measurements. The sensor is employed symmetrically with respect to the central axis to ensure that it can only sense normal pressure. Besides its high sensitivity, lightweight structure, and easy deployment, the stiff backing used to prevent its out-of-plane deformation often causes stiffness mismatch with the surrounding tissue and liner material. This mismatch can result in stress concentration at the sensor edges, causing local tension in the tissue of the residual limb [40]. Besides, Kulite sensors can only measure strains at the location where they are instrumented (*i.e.*, they are discrete or point sensors). They also need to be connected to a data acquisition system through electrical wirings. As a result, pressure measurement over a large area can only be achieved by employing an array of Kulite sensors on the residual limb [37]. However, such an implementation would restrict the range of motion of amputees and influence their normal gait, especially due to the large number of tethered electrical connections required. They are also susceptible to cross-talk due to their high stiffness.

To overcome these aforementioned limitations, Appoldt *et al.* [31] proposed a plunger-piston type force gage, where the gage-housing cylinder was placed inside the wall of the prosthesis by drilling a hole near the region of clinical interest. The piston was attached to a small steel beam whose ends were clamped to the main transducer frame. Similar to the diaphragm deflection transducer setup, four strain gages were arranged in a Wheatstone bridge configuration and employed for bending strain measurements, where normal stress was then evaluated using the measured bending strains. Although piston-type transducers are insensitive to cross-talk, they behave as a unidirectional transducer that is capable of only measuring direct pressure. The design of the socket also needs to be adjusted as the installation of piston-type transducers requires drilling holes in the wall of the prosthesis.

The total stress developed at the prosthesis-residual limb interface is a resultant of normal and shear stresses. Excessive shear stress between the residual limb and the prosthesis can cause reduced blood flow and skin-related issues [41]. Therefore, the measurement of shear stresses is just as important as measuring normal stresses. First shear stress measurement at the residual limb-socket interface was achieved by Appoldt *et al.* [32] by introducing a tangential pressure transducer in the wall of the socket. However, this system was unable to measure both normal and shear stresses simultaneously. The tangential pressure transducer needs to be replaced with the perpendicular pressure transducer for normal stress measurement.

Later, Sanders and Daly [42] developed transducers for simultaneous measurement of stresses in three orthogonal directions. The sensor was employed at four different locations within a prosthetic socket of a below-knee amputee for *in situ* stress measurement during gait. Each of the three transducers was oriented in three orthogonal directions over a 6.35-mm-diameter sensing area. Gages were employed on two opposite faces of an aluminum beam and a Wheatstone bridge network was formed. The shear force between the residual limb and the prosthesis was estimated from the measured difference in bending moment between the gage locations. The normal force was estimated by employing a full-bridge diaphragm strain gage network between the cap support and the Pelite disk. Besides achieving simultaneous measurements of normal and shear stresses, employment of piston-based transducer for *in situ* stress measurement at prosthesis-residual limb interface often gets hindered by its bulky size and intricate instrumentation. The design of strain gage-based *in situ* stress measuring systems was investigated and optimized by different groups of researchers [43-47].

2.2 Piezoresistive sensors

Piezoresistive force-sensing resistors (FSRs) are suitable for medical applications due to their thin, flexible, and conformable structure [48-50]. In general, FSRs are thin force sensors whose resistance decreases with applied normal forces [51]. The change in resistance is converted into a corresponding voltage output using the Wheatstone bridge configuration [52, 53]. FSRs can be made with different shapes, and they can measure the change in applied load. Stress is estimated by dividing the measured load with the surface area of the sensor. Being a thin sheet, piezoresistive sensors can be easily placed inside the socket for *in situ* pressure monitoring [54].

The Interlink FSR, LuSense PS3, and Tekscan FlexiForce A201 are three commercially available and most widely used FSRs. The Interlink FSRs are comprised of a conductive surface and inter-digitated electrodes [55]. Typically, their resistance changes from 1 M Ω to 10 K Ω for 1 N of applied load [56]. LuSense sensors come in different shapes and sizes with typical resistances that vary between 1 M Ω to 2 K Ω for sensing pressure between 0.5 and 100 N/cm² [57]. The FlexiForce A201 FSR consists of two layers of polyester/polyimide film, which are painted with conductive silver ink and laminated with adhesive to form the sensor [58]. While the Interlink FSRs are more robust, FlexiForce sensors exhibit better performance in terms of linearity, repeatability, time drift, and dynamic accuracy [59]. Like strain gages, piezoresistive FSRs are also point sensors. An array of FSRs is required to monitor distributed stresses acting on a large surface area such as the residual limb-prosthesis interface. For example, Ruda *et al.* [60] configured five Flexiforce sensors to form an array and embedded it in a flexible thin acetate sheet for distributed pressure monitoring at residual limb-prosthesis interface. However, stress measurements were not very accurate due to the small surface area of each FSR.

The two most widely used and commercially available piezoresistive pressure sensors for in-socket pressure measurements are the Rincoe Socket Fitting (RG Rincoe and Associates, Golden, CO, USA) [61] and F-Socket system [62]. Rincoe Socket Fitting consists of six sensor strips between the liner and the prosthesis, where each strip contains 10 discrete sensors separated by 1.5 in. Each sensor dot features a resolution of 0.5 psi up to 12 psi.

On the other hand, the FSR-based F-Socket system consists of 96 discrete sensing elements arranged in a 16 \times 6 matrix [63]. The large number of discrete sensors allows it to generate higher resolution pressure maps as compared to the Rincoe Socket System. Although the F-Socket system does not require intricate instrumentation, they need to be calibrated according to the manufacturer's instructions as was studied by Luo *et al.* [64].

Polliack *et al.* [62] compared the performance of Rincoe and F-socket systems for *in situ* stress measurements at the residual limb-prosthesis interface in terms of their accuracy, hysteresis, drift, and the effect of surface curvature. The experiments were performed in both flatbed and customized pressure vessels. The Rincoe Socket System exhibited an accuracy error of 25% (flatbed) and 33% (pressure vessel) with a corresponding 15% (flatbed) and 23% (pressure vessel) hysteresis error, and 7% (flatbed) and 11% (pressure vessel) drift error. The F-Socket system outputted 8% (flatbed) and 11% (pressure vessel) accuracy errors, 42% (flatbed) and 24% (pressure vessel) hysteresis errors, and 12% (flatbed) and 33% (pressure vessel) drift errors. These results suggest that the F-Socket system performed better. However, one of its main drawbacks is its inability to measure shear stresses [53]. In addition, it is susceptible to low-frequency response errors due to its hysteresis [30, 53].

2.3 Capacitive sensors

Aside from piezoresistive pressure sensors, capacitive sensors have also been employed for monitoring the pressure distribution at the residual limb-prosthesis interface [65-68]. The first capacitive interfacial stress sensor designed and implemented for this application was by Meier *et al.* [69]. The 2-mm-thick, flexible capacitance sensor exhibited an accuracy of 20%. Later, another prototype capacitance pressure sensor was designed by Polliack *et al.* [70] for prosthetic socket use, where 16 sensors were mounted in a $2.5 \times 2.5 \times 0.064$ cm³ silicone substrate in the form of a 4×4 matrix. The sensor array was highly flexible, capable of being stretched to 4%. It also featured a mean flatbed accuracy error of $2.42 \pm 3.20\%$, whereas the mean hysteresis errors for the flatbed tests were $12.93 \pm 4.63\%$. The mean hysteresis errors for the positive mould were similar at $12.95 \pm 8.26\%$. The prototype sensor demonstrated a mean flatbed drift error of $4.40 \pm 3.46\%$ and a positive mould drift error of $6.20 \pm 7.12\%$. These findings have proved the superiority and acceptability of capacitance-based pressure sensors over piezoresistive sensors for *in situ* stress measurements [93, 94]. However, these capacitance-based pressure sensors were still unidirectional and suitable for measuring only direct applied pressures.

A miniature capacitance-based triaxial load transducer was proposed by Williams *et al.* [71] for simultaneous measurement of normal and shear stresses on the socket wall. A 2 g-weight single element piezoelectric copolymer poly(vinylidene fluoride-trifluoroethylene) (P(VDF-TrFE))-based triaxial force transducer that was $10 \times 10 \times 2.7$ mm³ in size was proposed by Razian *et al.* [72]. This sensor was also able to measure normal and shear stresses simultaneously. Although they exhibited good sensitivity, linearity, less hysteresis, and low cross-talk, their temperature dependence and sophisticated manufacturing made it difficult for large-scale production and use for distributed pressure monitoring.

2.4 Optical sensors

Fiber Bragg grating (FBG) sensors offer high sensitivity, durability, multiplexability, immunity to electromagnetic interference, and resistance to the aggressive environment [73-80], and they have been widely used for measuring different quantities (*e.g.*, strain, temperature, humidity, force, and pressure, to name a few). Kanellos *et al.* [81] developed a highly-sensitive pressure sensor by embedding an FBG sensor in a thin polymeric sheet to form a $20 \times 20 \times 2.5$ mm³ sensing pad. This FBG sensor exhibited a maximum fractional pressure sensitivity of 12 MPa with a spatial resolution of 10×10 mm². It was operated in real-time and demonstrated minimum hysteresis. The same group of researchers found that the sensor pad's rigidity and durability are the two main fabrication parameters that can be tuned to enhance sensor reliability for in-socket applications [82].

As mentioned earlier, the stiffness of the matrix polymer influenced the performance of FBG sensors for stress measurements. Different matrix materials were investigated by Al-Fakih *et al.* [83] for attaining the most efficient and accurate stress measurements at the residual limb-prosthesis interface. The results revealed that harder and thicker matrix materials exhibit higher sensitivity and accuracy when used in the socket. In a separate study conducted by the same group [84], FBG elements were embedded in a thin layer of epoxy-based sensing pad for in-socket stress measurements. The FBG-instrumented epoxy pad was embedded in a silicone polymer to form an *in situ* pressure sensor. The performance of the FBG-epoxy sensor was tested by inserting and inflating a heavy-duty balloon into the socket using compressed air to simulate the similar condition of a transtibial amputee's patellar tendon bar. The sensors exhibited a sensitivity of 127 pm/N with full-scale output hysteresis of ~ 0.09 . This study validated the reliability of FBG-based pressure sensors for *in situ* pressure measurement. However, like many piezoresistive pressure sensors, most FBG-based pressure sensors could only measure normal stresses. Zhang *et al.* [85] reported a soft polymer-based FBG (PFBG) for simultaneously measuring shear and normal stresses. The sensor was fabricated with one horizontal and another inclined PFBG embedded in a soft polydimethylsiloxanes (PDMS) matrix. The proposed sensor was tested by simultaneously applying normal and shear forces. The measured pressure sensitivity was found to be 0.8 pm/Pa within the range of 2.4 kPa, and its shear stress sensitivity was reported to be 1.3 pm/Pa for a full range of 0.6 kPa.

Optoelectronic sensors have also been used for pressure monitoring at human-machine (*i.e.*, residual limb-prosthesis) interfaces. This type of sensors is made of an external silicone structure and a printed circuit board that contains an array of sensing elements. Each sensing element consists of a light transmitter, a light-emitting diode (LED), a

receiver, and a photodiode. The silicone cover serves as the main component for the transduction process. An applied load on the sensor deforms the silicone cover, hence exhibiting a proportional change in output voltage as the light intensity received by the photodiode. However, the performance of these sensors was not evaluated for socket prosthesis applications [86, 87].

Instead, a thin and flexible sensor foil was presented by Missinne *et al.* [88] to monitor shear stresses for medical applications. The sensor works on the principle of shear stress-dependent coupling change of optical power between a Vertical-Cavity Surface-Emitting Laser (VCSEL) and a photodiode that was separated by a deformable sensing layer of PDMS. Shear stresses up to 139 kPa were measured with a sensitivity of $-7.9 \mu\text{A/kPa}$ in the linear portion of its range. A new type of optoelectronic sensor was proposed by Lincoln *et al.* [89], which was fabricated using a commercially available integrated circuit, a printed circuit board, and layers of silicone elastomers. Comparatively lower sensor drift, hysteresis, and some temperature sensitivity were reported. A similar design principle was used by Cutkosky *et al.* [90], where a VCSEL and a photodiode were assembled in an ultra-thin package and separated by a deformable polymer sensing layer. A total of five sensors were employed for normal and shear force measurements: one for detecting normal loads, two for detecting shear force in one direction, and the last two for detecting shear in the orthogonal direction. As a normal load was applied to the reflective material, the interstitial transparent material compressed, and the reflective material moved the light source (emitter) closer to the light sensor (detector). This caused the detector to detect an increase in reflected light from the emitter. Shear loads were sensed by adding absorptive regions to the reflective layer. An applied shear load changed the ratio of absorptive to reflective material between the emitter and the detector, which changed the amount of light reflecting back to the detector. Despite this interesting sensing mechanism, optoelectronic sensors may become damaged during normal gait, and they are also susceptible to electromagnetic interference [91].

Different solutions have been proposed and implemented to mitigate stress-related issues at the residual limb-prosthesis interface. For example, a liner system was used as a sock to provide a better cushioning effect on the residual limb [92]. A sub-atmospheric suspension system was also used to reduce stress-related discomfort by more efficiently distributing the applied stresses [28]. The effect of brimless interface design was compared with ischial ramus containment (IRC) prosthetic sockets when using vacuum-assisted suspension on persons with a unilateral transfemoral amputation. The peak/stance mean pressure in the medial proximal aspect of the socket was 322 mmHg in the IRC, as compared to 190 mmHg in the brimless condition. Both systems provided better friction, thereby ensuring improved load transfer from the residual limb to the socket [23].

A variable-impedance prosthetic socket was proposed by Sengeh and Herr [93], which was able to reduce pressure intensities at critical locations in the socket. CAD-CAM were employed to fabricate the socket on the basis of biomechanical data obtained through magnetic resonance imaging (MRI). The depths of tissue in the residual limb was inversely estimated from MRI images and impedance characteristics, which were thereafter used to adjust the geometry and shape of the socket to reduce contact pressure near the bony prominence of the residual limb. Depending on the tissue condition of the residual limb, 7% to 21% reduction in pressure was achieved. However, this design process is computationally intensive and case-specific for every amputee.

Another design considered the incorporation of a magnetorheological (MR) fluid bag in the socket [27]. The volume of the socket was adjusted by controlling the volume of the MR fluid bags with external magnetic sources. A 100 kPa reduction in pressure was achieved by applying a 0.38 T magnetic field at the patella area of the socket-residual limb system. However, a bulky mechanical and electrical control system and the requirement of a high-energy power supply are the two main drawbacks of this smart socket system.

3 Temperature

Amputees with lower limb amputations often suffer from thermal discomfort during their regular activities, since the reduced surface area of the residual limb often influences the thermoregulatory system. This situation often amplifies the amputees' sweating rate, which invariably causes discomfort, irritations, and skin ulceration. In a recent study by Ghoseiri *et al.* [94], it has been reported that $\sim 52\%$ of the amputees with socket prostheses experience heat-related

problems and a 1 °C to 2 °C rise in temperature in their residual limb during regular activities. The mean skin temperature of all subjects at the start of the test was 31.4 ± 1.3 °C. The temperature rose by 0.8 °C and reached 32.2 ± 1.7 °C at the end of the 15 min resting period [95]. This increase in body temperature was mainly caused by the poor heat conduction property and moisture permeability of the socket materials (*i.e.*, the socket and the liner) [96]. Therefore, in addition to identifying socket materials that provided adequate frictional and stiffness properties, good heat conduction and moisture permeability should also be considered.

Ad hoc thermistors were integrated with a socket prosthesis to monitor the interfacial temperature between the residual limb and socket [97]. The in-socket temperature of five transtibial amputees at 14 different locations on the residual limb were investigated at four different stages (*i.e.*, donning, steady-state resting, initial walking, and steady-state walking). The results indicated that the thermal dissipation characteristics of the socket and liner restricted heat loss from the residual limb, and the temperature increase was larger in areas where there was more muscle bulk. In a separate study by Huff *et al.* [98], the temperature at the residual limb-prosthesis interface was measured for five transtibial amputees wearing different socket systems. The subjects were asked to sit for 15 min, followed by 10 min of treadmill walking. Temperature was measured using 14 thermistors, and 38-gage wires were employed for connecting them with the data acquisition system. The results indicated that temperature varied with activity and location on the limb. However, multiple wire failures were reported at the distal posterior location. In addition, the duration of the experiments was too short to reach steady-state temperature during the activities [97]. Thus, the experimental design was modified to better quantify temperature at the skin-prosthesis interface during a 2.5 h protocol that included periods of resting and activity [98]. Here, 16 Thermometrics MA100GG thermistors with 2-mm-sensor head diameter were connected to a data acquisition system with a BNC-2090 analog to digital (A/D) board. The 28-gage wires that connected the thermistors to the data acquisition system were used to reduce the incidence of wire failure. An average steady-state temperature of 29.5 ± 0.9 °C was recorded during the last minute of the 1-h rest period. The residual limb temperature increased to 32.6 ± 0.8 °C after 30 min of treadmill walking. The temperature reached a maximum of 32.8 °C and thereafter decreased to 32.6 ± 0.6 °C during the last minute of the final rest period. It was found that, at the end of the final 1-h rest period, skin temperature did not return to their initial rest period values.

Attempts have been made to mitigate these temperature-related issues by designing well-perforated fabrics that can be easily integrated with the socket and liner. A breathable liner system was proposed by Caldwell *et al.* [99] to mitigate problems due to heat and sweating in the socket. A silicone-based prosthesis liner was perforated to expel sweat and heat from the lower-limb prosthesis. Holes were intentionally made approximately 1 cm apart using a perforating tool. The initial clinical experience with this technique suggested that expulsion of sweat occurred, and user feedback indicated improved prosthesis performance. Bartlett *et al.* [100] proposed a new liner, which was made of spacer fabric in combination with a partial silicone coating, to maintain the functionality of the skin inside the socket. The temperature inside the socket was regulated based on the liner's permeability to gas and humidity. The sides of the prosthesis facing the skin were provided with bacteriostatic fibers that contained silver ions (Ag^+). Ag^+ prevents bacterial growth in the socket and helped reduced odors. Fibers with large surfaces were also included in the middle layer of the liner textile to expel moisture.

A phase change material (PCM) was incorporated in smartTemp liner [101]. It was reported that the mean increase in temperature of the residual limb during activity was 0.2 °C lower when wearing the smartTemp liner versus the placebo liner. Overall, the temperature was ~ 0.9 °C lower at the end of daily activities. A new cooling device that could maintain a constant temperature on the residual limb surface was proposed by Han *et al.* [102]. The excess metabolic heat in the residual limb was removed by a cooling pipe and dissipated to an external ice pack. A cooling capacity ranging from 6.6 W to 15.6 W was achieved by using a flow channel array. It was demonstrated that under two simulated walking activities, skin temperature was kept constant ($31.4^\circ\text{C} \pm 0.2^\circ\text{C}$) by using the proposed cooling system. These results demonstrated the device's ability of removing excess heat from the residual limb during regular physical activities of amputees. Ghoseiri *et al.* [103] proposed a smart thermoregulatory system for temperature control in the socket prosthesis. The system was designed and installed in a phantom model of a prosthetic socket. It captured temperature data from 16 discrete sensors positioned at the interface between the phantom model and a silicone liner. The average of the collected set of measurements was compared with a predefined temperature value in order for the system to apply necessary heating or cooling to achieve thermal equilibrium. A thin layer of aluminum sheet was used

to ensure good heat transfer between the thermal pump and sites around the phantom model. To decrease the prosthetic socket's thermal resistance, heat pipes were used to concentrate heat flux from the residual limb's skin surface to a cooling region on the outer surface of the socket where a compact heat sink was attached. A small fan was used to convect heat from the heat sink to the ambient surroundings. Experiments showed that the cooling capacity of the prototype device ranged from 2.1 W to 7.0 W at an ambient temperature of 23°C. The analysis showed that the device could potentially maintain a constant skin temperature for a 9.4 W thermal load [104]. Furthermore, the prosthetic socket was modified by incorporating a helical cooling channel within the socket wall using additive manufacturing [105]. Computer simulations and laboratory experiments were performed to assess the ability of the modified design to create a greater temperature difference across the socket wall. It was found that the modified socket exhibited greater temperature differences of 11.11 °C and 6.41 °C based on numerical simulations and experiments, respectively. These findings suggested that cooling channel-assisted prosthesis could provide effective temperature control of an amputee's residual limb.

Zhe *et al.* [106] proposed a modified socket with a heat pipe, including a working fluid and a wicking structure. The heat pipe had a socket section and a heat sink that was extended along its length through the socket wall. The working fluid had a boiling point from about 0 °C to 90 °C. The working fluid could be selected in such a way that it could evaporate to form vapor due to heat from the residual limb in the socket, thus drawing latent heat of vaporization from the residual limb. A porous wicking material, attached to a hypobaric assisted vacuum liner, was also suggested to allow moisture escapement [107]. A dedicated liner with different conical holes was proposed [108], where the holes were placed to eliminate moisture at the skin through airflow channels used also for the suspension.

4 Volume Fluctuations

The volume of the residual limb experiences short- and long-term changes due to fluid level fluctuations. Therefore, socket fitment should be optimized to consider these volume fluctuations. It was reported that a maximum decrease of 11% decrement and an increase of 7% in residual limb volume can be observed during an amputee's daily activities [109]. However, just a 3.5% volume change is sufficient to cause a high-level discomfort [110]. A decrease in the volume of the residual limb can lead to excessive relative displacement between the residual limb and socket. On the other hand, the amputee can experience excessive shear stress and normal pressure in the case of volume enhancement [109]. Different techniques are available for measuring volume fluctuations, including the use of water displacement techniques [111], optical scanning [112, 113], contact probes [114], ultrasound [115], computed tomography (CT) scanning [116], laser scanning [117], MRI [118], and bioimpedance measurements [119].

Inflatable insert products were used to overcome volume change of the residual limb under compressive loading conditions. Sanders *et al.* [120] reviewed the mechanical features of commercially available air-filled bladders. Pressure-loss tests under static loading demonstrated that, after inserts were inflated to 43.4 kPa to 45.6 kPa, insert pressures reduced from 0.09%/min to 1.36%/min in the first 5 min and from 0.00%/min to 0.27%/min in the subsequent 55 min. This result suggests that the stress to resist insert expansion was absorbed by the residual limb and socket versus than by the insert itself. However, high air pressure should be maintained throughout the process to mitigate the effect of volume fluctuation of the residual limb. Underinflation could result in inadequate support, while overinflation could induce localized tissue compression [121]. On the other hand, Carrigan *et al.* [122] showed an effort to develop adjustable inserts that consisted of arrays of small, sensorized, inflatable pressure actuators. Here, an F-Socket system was used to measure the pressure distribution at the residual limb-prosthesis interface. An air supply, comprising of a pump and air pressure regulator, was distributed to the inserts through a solenoid manifold to control each individual actuator on the basis of the measured pressure distribution. The actuators then expanded in response to residual limb volume change.

It was arguably more challenging to control volume change by means of air inflation than by using fluid [123]. A fluid-controlled actuation system was proposed by Greenwald *et al.* [121] to compensate for the residual limb's volume change. The system consists of a fluid reservoir, a mechanical control circuit, and an array of discrete bladders located inside the socket. Water was used as the working fluid, which was drawn from the reservoir and supplied to the bladders. Another fluidic solution was one based on MR fluids [27]. Fluidic flexible matrix composite wafers

(f2mc) were integrated into the prosthetic socket for volume regulation. These wafers were connected to a reservoir, and contain an internal fluid. Fluid flow between the tubes and reservoir was controlled by valves. The f2mc demonstrated more than 300% increase in volume and potentially several orders of magnitudes of changes in stiffness. The experiments conducted using a prosthetic socket showed that the flexible matrix composite wafers could be used to mitigate the effects of volume changes [124].

Instead of an active actuation system, the mechanical design of the socket can also be modified to mitigate the effects of residual limb volume fluctuations. A movable panel-based socket system was introduced by several researchers, where fitment could be adjusted manually through the use of straps [125, 126] and clamps [127, 128]. The Infinite Socket™ (LIM Innovations, San Francisco, CA, USA) is a commercially available, adjustable, custom-molded, four-strut design combined with a textile brim and tensioner [129]. The dynamic frame of the Infinite socket™ has a textile interface that is low in friction, anti-microbial, durable, and washable [28]. Adjustments can be made by both the clinicians and patients to manage long-term and daily volume fluctuations. The pivoting and sliding connection between the struts and base provides additional flexibility in adjustability and shock absorption. However, to avoid excessive tightening, which could result in severe consequences over time (*e.g.*, stump deformation and mass loss), these prosthetic systems should evolve and become fully automated and self-adjustable based on sensor inputs.

5 Other Socket Issues and Their Solutions

Although the aforementioned factors are the three key parameters that need to be monitored for maximizing amputee comfort, there exist other issues that also affect socket and amputee performance. For instance, walking on varying terrains remains challenging for amputees with lower limb amputations. Different structural components of the amputated lower limb (*e.g.*, ankle joint) are adaptive in nature, which can change their stiffness to perform dorsiflexion–plantarflexion and provide propulsion power for walking. Conventional socket prostheses today do not provide such adaptive features, which results in amputees suffering from poor gait during activities such as normal walking. Therefore, monitoring gait patterns and gait phases could be useful for future designs of advanced prosthetic systems, especially if next-generation smart socket prostheses contain actuators and dampers that require sensory feedback for achieving optimal control. On the other hand, the skin on the residual limb are vulnerable to skin-related issues and infections. If a good skin condition cannot be ensured, infection can occur, and the prosthesis cannot be worn. In this section, sensing technologies and measurement strategies to monitor and assist gait are briefly reviewed. Infection monitoring strategies are also summarized.

5.1 Gait monitoring and assistive technologies

Among many data collection methods used for gait analysis, the stereometric method is the most popular and widely used [130]. Visible markers are attached directly onto the skin of the body, and their motions are tracked through imaging equipment. In general, charge-coupled device (CCD) cameras and frame-grabber electronics are employed to capture digital images of the amputees while walking. Digital image analysis is performed to extract the exact location of the markers using triangulation of different camera viewpoints. For example, a VICON commercial system was used by Koktas *et al.* [131] for gait analysis. Amputees were asked to walk on the platform. Temporal change of joint angles, joint moments, joint powers, force ratios, and time-distance parameters were recorded. In this study, a semi-automated gait classification system was designed and implemented for gait analysis. The gait data were categorized by combining the joint angle and time-distance data by multilayer perceptrons (MLPs) classifiers. In general, since this technique uses visual markers and does not require active sensors to be attached to the patient, this technique has a minimum effect on the natural motion of the amputees. However, multiple sets of walking data need to be collected to study the amputee's gait pattern, since it cannot be quantified from a single traversal of the instrumented walkway [130]. Furthermore, prolonged walking on the walkway may cause amputee fatigue.

Besides such video-based gait analysis methods, the automatic classification of gait phases has been done using FSRs. An FSR-based on-shoe device was proposed by Morris *et al.* [132] for continuous and real-time monitoring of gait. Wireless transmission of the measured data was achieved to provide real-time information about the three-dimensional motion, position, and pressure distribution of the foot. A pattern recognition algorithm was implemented to analyze the collected data in real-time, and the results were compared with a commercial optical gait analysis system. Although FSRs embedded in the shoe soles can serve as footswitches [133], they often fail to classify foot flat [134].

On the other hand, Williamson and Andrews [135] used accelerometers for gait event detection. An array of accelerometers was worn by a subject on the shank of the leg. The ADXL05 uniaxial accelerometer was selected for its high signal-to-noise ratio. A 12-bit analog to digital converter (NI-DAQ AT-MIO 16L board, National Instruments Inc.) with a sampling frequency of 100 Hz was employed to record the signals. It was demonstrated that the vibration data measured by the accelerometers could be used to train a machine-learning algorithm to reliably detect the various phases of gait. Similarly, built-in accelerometers in smart mobile devices were also used for gait measurements. Today, many smart mobile devices have accelerometers to detect their orientation. Chan *et al.* [136] explored the capabilities of the embedded accelerometers of iPhones to identify different gait events, while the subject was engaged to walk along a flat surface. It was shown that iPhone-recorded acceleration data could be used to detect steps, stride time, and cadence. However, the position of the iPhone should be judiciously selected to obtain the most meaningful acceleration data with minimal noise.

Since the lower limb's angular velocity has distinct signal features during heel-strike and toe-off [134], Aminian *et al.* [137] used a gyroscope to measure the angular movement of the lower limbs of subjects during walking. In short, a gyroscope consists of a vibrating component coupled with a sensing element for Coriolis force measurement. The study was intended to estimate spatial-temporal parameters during long periods of walking. Three miniature low-power piezoelectric gyroscopes (Murata, ENC-03J) were used for measurements. The measured signals were amplified, and noise was removed with a low-pass filter. The gyroscopes were directly mounted to each shank and the right thigh of the amputees using a rubber band. The signals were digitized using a portable data logger (Physilog, BioAGM, CH) that sampled data at 200 Hz. A wavelet transformation-based algorithm was implemented to compute gait parameters from the measured angular velocities of the lower limbs. In contrast to accelerometers, gyroscope measurements do not depend on the position of the sensors. [138] The gyroscope-measured angular velocity is less noisy, since rotational motion is calculated by integrating the recorded data. However, gyroscope measurement is sensitive to shock due to the mechanical fastening of the beam inside the gyroscope.

In addition to measure the angular motion of the residual limb, it is important to estimate the forces exerted by the residual limb on the socket prostheses during walking for analyzing the gait cycle [134]. Pappas *et al.* [139] employed three FSRs with a miniature gyroscope for force and angular velocity measurements during gait cycles. The FSRs were employed to measure load on a shoe insole, and the gyroscope measured the rotational velocity of the foot. Indoor and outdoor experiments were performed on subjects with impaired gaits. It was shown that the system could accurately and reliably detect various phases of gait (*e.g.*, stance, heel-off, swing, and heel-strike). In addition, the proposed method could distinguish between the feet sliding and true walking, as well as shifting of the weight from one leg to the other.

Apart from motion and force measuring sensors, different kinds of stimuli are also used to study the motion of the residual limb within socket prostheses during gait. Radiographic techniques were used by several groups to analyze residual tibial movement within transtibial sockets [140-142] and residual femoral movement within transfemoral sockets [143-145]. However, ionizing radiation used in radiography limits its application for gait monitoring of amputees. As a result, they are only used for static analysis at simulated instants of the gait cycle. Since ultrasound does not have any known detrimental health effects, it was used to monitor the static position of the residual femur in transfemoral sockets during gait [146]. Measurements were recorded from two simultaneously transmitting ultrasound transducers. It was found that the pattern of femoral motion was consistent with a rapid change in motion during the early and late prosthetic stance phase. However, this method was unable to determine the correct orientation of the socket relative to the ground from a partial gait analysis study.

In addition to the variety of sensing technologies for gait monitoring, researchers have proposed various systems for assisting patients with impaired gait. For example, Ward *et al.* [147] developed a modified walking frame with a linkage system to assist patients to perform normal gait. The device was named the R-Link Trainer (RLT). It was found that peak hip extension and knee flexion were reduced bilaterally when walking with the RLT. Constrained limb (*i.e.*, the left limb) experienced a significantly increased peak hip flexion, while peak plantarflexion was significantly reduced. The right limb experienced a late peak knee flexion and plantarflexion. A significant bilateral reduction in peak electromyography amplitude occurred when walking in the RLT. This study validated that RLT imposes significant constraints along with asymmetries in lower limb kinematics and muscle activity patterns. McDaid

et al. [148] presented a multi-input multi-output (MIOM) force controller for ankle rehabilitation. This MIMO actuator force controller was designed in such a way that the gains along the decoupled directions could be pushed closer to their corresponding gain margins. Kora *et al.* [149] developed a new gait rehabilitation device termed the “Linkage Design Gait Trainer,” which was based on a simple walking frame. This frame was designed following the four-bar linkage “end-effector” mechanism to generate normal gait trajectories during daily activities. It was shown that the proposed mechanism could assist the leg of the user during over-ground walking. Although these gait assisting technologies were not proposed for amputees with socket prostheses, their designs and implementation procedures could be adjusted in the future to serve such purposes.

5.2 Infection monitoring

Besides gait monitoring, inflammation and infection monitoring in the residual limb is also important for patients living with socket prostheses. Cutti *et al.* [150] explored the potential of infrared thermography with wearable devices to monitor the temperature and relative humidity inside the socket. A thermal imaging camera was employed to measure the superficial temperature distribution of the residual limb. Parallel measurements through thermal imaging cameras and wearable sensors provided complimentary information. A 20% increment in hot areas were found after walking as compared to resting. Humidity inside the socket increased $\sim 4.1 \pm 2.3\%$ because of the sweat produced. Increased temperature and excessive humidity inside the socket prostheses could be a sign of skin inflammation and infection. Hence, temperature and humidity monitoring inside the socket could be useful for early prevention of skin-related issues in the residual limb.

There is little published data related to the diagnosis of stump infections. It was found that poor hygiene is responsible for most of the bacterial and fungus infections in the residual limb of the amputees [151]. Regular inspection and cleaning of the residual limb can prevent most of infections caused by various microorganisms. A so-called “sausage-toe”-like red swollen mark on the stump often indicate an infection in the form of osteomyelitis [152]. Physicians generally perform a “probe-to-bone” test, where a sterile blunt metal probe is used to probe an ulcer in the residual limb. A gritty or stony feeling of bone indicates the presence of osteomyelitis [153, 154]. Besides such clinical diagnostic approaches, blood tests are often performed to identify infections in the human body. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are extensively used to detect infections [155]. Three-phase technetium bone scanning, leukocyte scanning, labeled immunoglobulins, and labeled anti-white cell monoclonal antibodies are some of the widely used isotope scanning scintigraphy techniques for infection diagnosis [156, 157]. Despite some promising results, none of them has emerged as a reliable, robust, and useful method for infection detection, especially if monitoring is needed over extended periods of time.

In addition to the aforementioned methods, imaging of the residual limb can be helpful for early detection of infection in the residual limb [158]. Traditional X-ray imaging could be beneficial for detecting infection in the residual limb. By using X-ray imaging, the condition of the skeletal and soft tissues could be monitored [159]. Computed tomography (CT) and magnetic resonance imaging (MRI) are two of the most widely used imaging techniques to detect subcutaneous infection in the human body [158, 160]. Although MRI is considered the best imaging modality for diagnosis of various infections, there could be problems related to the interpretation of MRI images, especially after any surgery or due to artifacts produced by metallic implants [161, 162]. Dutronc *et al.* [163] made an observational study on 72 patients with lower-limb amputation. Ultrasonography and CT scan coupled with fistulography were used to diagnose the extension of infection. It was found that 44% of the patients needed surgical revision in addition to antibiotic treatment. Although these imaging techniques have high accuracy and reliability, the patients need to visit specialized facilities for imaging and for receiving treatment. The imaging instruments are also bulky, which eliminates the possibility of *in situ* applications. Furthermore, a patient’s residual limb needs to be exposed to harmful radiation that would cause detrimental health effects at high doses.

Among all of these abovementioned techniques, bone-biopsy is regarded as the most robust method to detect infection. Specimens are obtained from a previously unexposed bone to culture the bacteria to determine the cause of infection. However, a limited amount of materials obtained for culture can be problematic as it may cause false-negative results [164, 165].

On the other hand, infection often occurs due to microbial attack, which causes a change in pH of the infected cells [166]. Gupta and Loh [167] developed a pH-sensitive nanocomposite thin film sensor for monitoring infection in implantable prostheses. Thin films can be deposited onto the surface of osseointegrated prostheses prior to the implant surgery and can stay inside the human body, functioning as a passive (unpowered) sensor. The dielectric property of the thin film changes due to a change in pH of its surroundings in response to infection. A noncontact, portable, and radiation-free imaging technique was developed and implemented to map the cross-sectional distribution of dielectric properties of the residual limb and embedded passive sensor. Experimental test results showed that the proposed electrical capacitance tomography approach could detect changing pH environments in a noncontact fashion. Although this technique was proposed for infection monitoring at the tissue-prosthesis interface of the amputees with osseointegrated prostheses, its application can be potentially extended for socket prosthesis applications.

6 Future Outlook

In general, there still remains a significant challenge around data. An important basis for optimal acute and long-term management of amputees is an in-depth understanding of the patient and the functional consequences of the amputation. A comprehensive understanding of the amputee and their environment, as well as sound objectives and functional outcome measures, are important to obtain. Establishing prosthetic socket effectiveness guidelines will provide a much-needed tool to deliver the best prosthetic care to individuals who have sustained lower limb extremity loss. Sensor technology provides the next technological solution to explore and address this lack of data. Understanding the integration of sensor technology with prosthetic devices and their ability to relay real-time biological and mechanical data to the amputee will be a key concept in the rehabilitative process. The strategy of leveraging cloud computing algorithms and machine learning to process and relay this information to an end-user application will have vast implications including the opportunity to use telehealth platforms, the potential integration of patient-reported outcomes into electronic health record (HER) systems and the ability to improve the collection clinical outcome metrics. The goal is to include early identification of physical conditions affecting performance and efficient recovery to optimize physical wellness.

As discussed earlier, many of the sensors used today are point sensors and focus only on measuring a single parameter. Nanotechnology-enabled sensors can potentially provide more suitable sensing solutions for next-generation socket prostheses. For example, Wang *et al.* [19, 168] developed a fabric-based sensor that conforms to the interior of a socket prosthesis and maps the pressure distribution at the human-socket interface. The carbon nanotube-based thin film sensor can be integrated with socket liners, while electrical impedance tomography could map pressure distributions using only a limited number of measurements. Furthermore, bioimpedance measurements can also be implemented to provide deeper insights regarding limb conditions and volume fluctuations. However, this technique has not yet transitioned from the research arena to clinical practice. More research is required to design appropriate instruments, clinical protocols, and algorithms to interpret bioimpedance sensor data. Overall, the future direction points to the development of multi-modal sensors that can selectively and simultaneously measure multiple parameters necessary for assessing residual limb health and socket performance.

The development of higher performance sensors and real-time sensors that offer distributed measurement capabilities and more data will ultimately provide more detailed information regarding residual limb health. These sensing streams will serve as the basis for which self-adjusting sockets can be realized, where socket and liner properties (*e.g.*, stiffness) can be autonomously varied to ensure optimal fitment and comfort. For example, an electromagnetic excitation system can be actuated based on recorded pressure maps to selectively alter the stiffness of MR fluid at precise locations [169]. Such smart sockets that feature active stiffness modulation and a sensor-driven closed-loop control system can simultaneously address pressure-, temperature-, and volume-related issues autonomously. Besides relieving pressure hotspots and accommodating changes in limb volumes, future smart sockets should be able to adjust their properties for maximizing patient comfort.

Realization of smart socket prostheses further opens up opportunities for developing a “digital twin” of the residual limb and socket system or of the patient as a whole. A digital twin is a digital representation of a physical object or

system [170]. Today, digital twins have been developed and proposed for a wide variety of systems such as buildings, factories, airplane, and space shuttles. This concept can be further expanded for an amputee's residual limb and socket to better understand and predict patient comfort and health. Information acquired from different digital twins can also help refine and guide future smart socket designs. Digital twin simulations can be conducted to characterize how different socket designs and inputs would affect socket performance. For instance, physicians can use the digital twin to test socket alterations before implementing them in clinical settings.

7 Summary

Lower limb prostheses have significantly advanced in all respects except for the socket, but traditional prosthetic socket technology and methods have seen little advancement in the past 50 years. The inability for conventional sockets to respond to the daily needs of amputees leads to short-term and long-term consequences. In fact, most amputees require multiple replacement sockets per year, with many amputees abandoning their socket prostheses due to discomfort and poor fitment. It has been found that volume fluctuations, unequal stress distributions at the residual limb-socket interface, and temperature inside the socket prosthesis are major issues that ultimately lead to amputees abandoning their prostheses. As discussed earlier, interfacial stress at the residual limb-prosthesis interface should be measured. Similarly, proper and comfortable socket fitment of the socket is challenging due to volume fluctuations of the residual limb, especially during the early post-surgery period [171]. Thus, the development and integration of advanced materials, electronic systems, miniaturized distributed sensors, and efficient actuators will pave way for the design of next-generation smart sockets. These smart sockets will not only be able to sense the level of amputee discomfort but will also be able to self-adjust itself to relieve interfacial stresses, volume changes, and temperature fluctuations in real-time.

Conflicts of Interest

Dr. Andrew Pedtke is the co-founder and chief executive officer of LIM Innovations. Prof. Kenneth Loh and Mr. Sumit Gupta declare no conflicts of interest.

References

1. Owings MF, and Kozak LJ. Ambulatory and inpatient procedures in the United States, 1996. *Vital and Health Statistics*. 1998; 13(139): 1-119.
2. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, and Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Archives of Physical Medicine and Rehabilitation*. 2008; 89(3): 422-429.
3. Stinner DJ, Burns TC, Kirk KL, Scoville CR, Ficke JR, and Hsu JR. Prevalence of late amputations during the current conflicts in afghanistan and iraq. *Military Medicine*. 2010; 175(12): 1027-1029.
4. Raichle KA, Hanley MA, Molton I, Kadel NJ, Campbell K, Phelps E, Ehde D, and Smith DG. Prosthesis use in persons with lower and upper-limb amputation. *Journal of Rehabilitation Research and Development*. 2008; 45(7): 961-972.
5. Akarsu S, Tekin L, Safaz I, Göktepe AS, and Yazicioğlu K. Quality of life and functionality after lower limb amputations: Comparison between uni- vs. Bilateral amputee patients. *Prosthetics and Orthotics International*. 2013; 37(1): 9-13.
6. Reiber GE, McFarland LV, Hubbard S, Maynard C, Blough DK, Gambel JM, and Smith DG. Servicemembers and veterans with major traumatic limb loss from vietnam war and oif/oef conflicts: Survey methods, participants, and summary findings. *Journal of Rehabilitation Research and Development*. 2010; 47(4): 275-298.
7. Roffman CE, Buchanan J, Allison GT, and 224-231. Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: Development and validation of clinical prediction rules. *Journal of Physiotherapy*. 2014; 60(4): 224-231.
8. Gailey R, McFarland LV, Cooper RA, Czerniecki J, Gambel JM, Hubbard S, Maynard C, Smith DG, Raya M, and Reiber GE. Unilateral lower-limb loss: Prosthetic device use and functional outcomes in servicemembers from vietnam war and oif/oef conflicts. *Journal of Rehabilitation Research & Development*. 2010; 47(4): 317-332.
9. Paternò L, Ibrahimi M, Gruppioni E, Mencias A, and Ricotti L. Sockets for limb prostheses: A review of existing technologies and open challenges. *IEEE Transactions on Biomedical Engineering*. 2018; 65(9): 1996-2010.
10. Durmus D, Safaz I, Adıgüzel E, A.Uran, Sarısoy G, Goktepe AS, and Tan AK. The relationship between prosthesis use, phantom pain and psychiatric symptoms in male traumatic limb amputees. *Comprehensive Psychiatry*. 2015; 1(59): 45-53.
11. Chamlian TR. Use of prostheses in lower limb amputee patients due to peripheral arterial disease. *Einstein (São Paulo)*. 2014; 12(4): 440-446.

12. Pasquina CP, Carvalho AJ, and Sheehan TP. Ethics in rehabilitation: Access to prosthetics and quality care following amputation. *AMA Journal of Ethics*. 17(6): 535-546.
13. Pinzur MS, Cox W, Kaiser J, Morris T, A.Patwardhan, and Vrbos L. The effect of prosthetic alignment on relative limb loading in persons with trans-tibial amputation: A preliminary report. *Journal of Rehabilitation Research & Development*. 1995; 32(4): 373-377.
14. T.Schmalz, Blumentritt S, and Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait:: The influence of prosthetic alignment and different prosthetic components. *Gait & Posture*. 2002; 16(3): 255-263.
15. Al-Fakih E, Osman NA, and Adikan FM. Techniques for interface stress measurements within prosthetic sockets of transtibial amputees: A review of the past 50 years of research. *Sensors*. 2016; 16(7): 1119.
16. Gaine WJ, Smart C, and Bransby-Zachary M. Upper limb traumatic amputees: Review of prosthetic use. *Journal of Hand Surgery*. 1997; 22(1): 73-76.
17. Petron A, Duval JF, and Herr H. Multi-indenter device for in vivo biomechanical tissue measurement. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 25(5): 4326-435.
18. Pirouzi G, Osman A, Azuan N, Oshkour A, Ali S, Gholizadeh H, and Abas WW. Development of an air pneumatic suspension system for transtibial prostheses. *Sensors*. 2014; 14(9): 16754-16765.
19. Wang L, and Loh KJ. Nanocomposite fabric sensors for socket prostheses and pressure ulcer prevention, *Conf Proc 7th World Conference on Structural Control and Monitoring*. 2018.
20. Meulenbelt HE, Geertzen JH, Jonkman MF, and Dijkstra PU. Determinants of skin problems of the stump in lower-limb amputees. *Archives of Physical Medicine and Rehabilitation*. 2009; 90(1): 74-81.
21. Levy SW. Skin problems of the leg amputee. *Prosthetics and Orthotics International*. 4(1): 37-44.
22. Lyon CC, Kulkarni J, Zimerson E, Ross EV, and M. H. B. Skin disorders in amputees. *Journal of the American Academy of Dermatology*. 2000; 42(3): 501-507.
23. Mak AF, Zhang M, and Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: A review. *Journal of Rehabilitation Research and Development*. 2001; 38(2): 161-174.
24. Ali S, Osman NA, Eshraghi A, Gholizadeh H, and Abas WA. Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction. *Clinical Biomechanics*. 2013; 28(9-10): 994-999.
25. Lee WC, Zhang M, and Mak AF. Regional differences in pain threshold and tolerance of the transtibial residual limb: Including the effects of age and interface material. *Archives of Physical Medicine and Rehabilitation*. 2005; 86(4): 641-649.
26. Colombo G, Facchetti G, and Rizzi C. Automatic below-knee prosthesis socket design: A preliminary approach, *Conf Proc International Conference on Digital Human Modeling and Applications in Health, Safety, Ergonomics and Risk Management*. 2016; 75-81.
27. Ogawa A, Obinata G, Hase K, Dutta A, and Nakagawa M. Design of lower limb prosthesis with contact pressure adjustment by mr fluid, *Conf Proc 30th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. 2008.
28. Kahle JT, and Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: Ischial containment versus brimless. *Journal of Rehabilitation Research and Development*. 2013; 50(9): 1241-1252.
29. Lu N, Lu C, Yang S, and Rogers J. Highly sensitive skin-mountable strain gauges based entirely on elastomers. *Advanced Functional Materials*. 2012; 22(19): 4044-4050.
30. Tiwana MI, Redmond SJ, and Lovell NH. A review of tactile sensing technologies with applications in biomedical engineering. *Sensors and Actuators A: Physical*. 2012; 179: 17-31.
31. Appoldt F, Bennett L, and Contini R. Stump-socket pressure in lower extremity prostheses. *Journal of Biomechanics*. 1968; 1(4): 247-257.
32. Appoldt FA, Bennett L, and Contini R. Tangential pressure measurements in above-knee suction sockets. *Bulletin of Prosthetics Research*. 1970; 10(13): 70-86.
33. Burgess EM, and Moore AJ. Physiological suspension: An interim report. *Bulletin of Prosthetics Research*. 1977; 58-70.
34. Leavitt LA, Peterson CR, Canzoneri J, Pza R, Muilenburg AL, and Rhyne VT. Quantitative method to measure the relationship between prosthetic gait and the forces produced at the stump-socket interface. *American Journal of Physical Medicine & Rehabilitation*. 1970; 49(3): 192-203.
35. Leavitt LA, Zuniga EN, Calvert JC, Canzoneri J, and Peterson CR. Gait analysis and tissue-socket interface pressures in above-knee amputees. *Southern Medical Journal*. 1972; 65(10): 1197.
36. Pearson JR, Holmgren G, March L, and Oberg K. Pressures in critical regions of the below-knee patellar-tendon-bearing prosthesis. *Bulletin of Prosthetics Research*. 1973; 10(19): 52-76.
37. Rae JW, and Cockrell JL. Interface pressure and stress distribution in prosthetic fitting. *Bulletin of Prosthetics Research*. 1971; 10(15): 64-111.
38. Sonck WA, Cockrell JL, and Koepke GH. Effect of liner materials on interface pressures in below-knee prostheses. *Archives of Physical Medicine and Rehabilitation*. 1970; 51(11): 666-669.
39. Winarski DJ, and Pearson JR. Least-squares matrix correlations between stump stresses and prosthesis loads for below-knee amputees. *Journal of Biomechanical Engineering*. 1987; 109(3): 238-246.
40. Dickinson AS, Steer JW, and Worsley PR. Finite element analysis of the amputated lower limb: A systematic review and recommendations. *Medical Engineering and Physics*. 2017; 43: 1-8.
41. Zhang M, Turner-Smith A, Tanner A, and Roberts V. Clinical investigation of the pressure and shear stress on the trans-tibial stump with a prosthesis. *Medical Engineering and Physics*. 1998; 20: 188-198.
42. Sanders JE, and Daly CH. Measurement of stresses in three orthogonal directions at the residual limb-prosthetic socket interface. *IEEE Transactions on Rehabilitation Engineering*. 1993; 1(2): 79-85.
43. Dou P, Jia X, Suo S, R.Wang, and Zhang M. Pressure distribution at the stump/socket interface in transtibial amputees during walking on stairs, slope and non-flat road. *Clinical Biomechanics*. 2006; 21(10): 1067-1073.
44. Hafner BJ, and Sanders JE. Considerations for development of sensing and monitoring tools to facilitate treatment and care of persons with lower limb loss. *Journal of Rehabilitation Research and Development*. 2014; 51(1): 1-14.
45. Osman NA, W. D. S, Solomonidis SE, Paul JP, and Weir AM. The patellar tendon bar! Is it a necessary feature? *Medical Engineering & Physics*. 2010; 32(7): 760-765.

46. Sanders JE, Lain D, Dralle AJ, and Okumura R. Interface pressures and shear stresses at thirteen socket sites on two persons with transtibial amputation. *Journal of Rehabilitation Research and Development*. 1997; 1(34): 19-43.
47. Sanders JE, Zachariah SG, Jacobsen AK, and Ferguson JR. Changes in interface pressures and shear stresses over time on trans-tibial amputee subjects ambulating with prosthetic limbs: Comparison of diurnal and six-month differences. *Journal of Biomechanics*. 38(8): 1566-1573.
48. Parmar S, Khodasevych I, and Troynikov O. Evaluation of flexible force sensors for pressure monitoring in treatment of chronic venous disorders. *Sensors*. 2017; 17(8): 1923.
49. Almassri AM, Hasan WZ, S. A. A, Ishak AJ, Ghazali AM, Talib DN, and Wada C. Pressure sensor: State of the art, design, and application for robotic hand. *Journal of Sensors*. 2015; 2015.
50. Schofield JS, Evans KR, Hebert JS, Marasco PD, and Carey JP. The effect of biomechanical variables on force sensitive resistor error: Implications for calibration and improved accuracy. *Journal of biomechanics*. 2016; 49(5): 786-792.
51. Fraden J. *Handbook of modern sensors. Physics, design and applications*. San Diego, CA: Springer; 2004.
52. Barlian AA, Park WT, Mallon JR, Rastegar AJ, and Pruitt BL. Semiconductor piezoresistance for microsystems. *Proceedings of the IEEE*. 2009; 97(3): 513-552.
53. Saccomandi P, Schena E, Oddo CM, Zollo L, Silvestri S, and Guglielmelli E. Microfabricated tactile sensors for biomedical applications: A review. *Biosensors*. 2014; 4(4): 422-448.
54. Dabbling JG, Filatov A, and Wheeler JW. Static and cyclic performance evaluation of sensors for human interface pressure measurement, *Conf Proc Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. 2012; 162-165.
55. Hollinger A, and Wanderley MM. Evaluation of commercial force-sensing resistors, *Conf Proc International Conference on New Interfaces for Musical Expression*. 2006.
56. Interlink Electronics Inc. FSR 400 series data sheet. https://www.interlinkelectronics.com/datasheets/Datasheet_FSR.pdf. Accessed 17 July 2019.
57. IEE International Electronics & Engineering. Specification sheet for standard LuSense sensors of the PS3 family. Revision 0, March 29, 2001.
58. Tekscan Inc. <https://www.tekscan.com/products-solutions/force-sensors/a301>. Accessed 3 July 2019.
59. Vecchi F, Freschi C, Micera S, Sabatini A, Dario P, and Sacchetti R. Experimental evaluation of two commercial force sensors for applications in biomechanics and motor control, *Conf Proc 5th Annual Conference of the International Functional Electrical Stimulation Society*. 2000.
60. Ruda EM, Sanchez OFA, Mejia JCH, Gomez SJ, and Flautero OIC. Design process of mechatronic device for measuring the stump stresses on a lower limb amputee, *Conf Proc 22nd International Congress of Mechanical Engineering (COBEM 2013)*. 2013; 4620-4628.
61. Polliack A, Landsberger S, McNeal D, Sieh R, Craig D, and Ayyappa E. Socket measurement systems perform under pressure. *Biomechanics*. 1999; 6: 71-80.
62. Polliack AA, Sieh RC, Craig DD, Landsberger S, McNeil DR, and Ayyappa E. Scientific validation of two commercial pressure sensor systems for prosthetic socket fit. *Prosthetics and Orthotics International*. 2000; 24(1): 63-73.
63. Almassri AM, Hasan W, Ahmad S, Ishak A, Ghazali A, Talib D, and Wada C. Pressure sensor: State of the art, design, and application for robotic hand. *Journal of Sensors*. 2015; 2015.
64. Luo ZP, Berglund LJ, and An KN. Validation of f-scan pressure sensor system: A technical note. *Journal of Rehabilitation Research and Development*. 1998; 35(2): 186-191.
65. Lai CH, and Li-Tsang CW. Validation of the pliance x system in measuring interface pressure generated by pressure garment. *Burns*. 35(6): 845-851.
66. Safari MR, Tafti N, and Aminian G. Socket interface pressure and amputee reported outcomes for comfortable and uncomfortable conditions of patellar tendon bearing socket: A pilot study. *Assistive Technology*. 2015; 27(1): 24-31.
67. Tiwana MI, Shashank A, Redmond SJ, and Lovell NH. Characterization of a capacitive tactile shear sensor for application in robotic and upper limb prostheses. *Sensors and Actuators A: Physical*. 2011; 165(2): 164-172.
68. Wolf SI, Alimusaj M, Fradet L, Siegel J, and Braatz F. Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot. *Clinical Biomechanics*. 2009; 24(10): 860-865.
69. 3rd RHM, Jr EDM, and Herman RM. Stump-socket fit of below-knee prostheses: Comparison of three methods of measurement. *Archives of Physical Medicine and Rehabilitation*. 1973; 54(12): 553-558.
70. Polliack A, Craig D, Sieh R, Landsberger S, and McNeal D. Laboratory and clinical tests of a prototype pressure sensor for clinical assessment of prosthetic socket fit. *Prosthetics and Orthotics International*. 2002; 26(1): 23-34.
71. Williams RB, Porter D, Roberts VC, and Regan JF. Triaxial force transducer for investigating stresses at the stump/socket interface. *Medical and Biological Engineering and Computing*. 1992; 30(1): 89-96.
72. Razian MA, and Pepper MG. Design, development, and characteristics of an in-shoe triaxial pressure measurement transducer utilizing a single element of piezoelectric copolymer film. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 2003; 11(3): 288-293.
73. Rocha RP, Gomes JM, Carmo JP, Silva AF, and Correia JH. Low-cost/high-reproducibility flexible sensor based on photonics for strain measuring. *Optics & Laser Technology*. 2014; 56: 278-284.
74. Fresvig T, Ludvigsen P, Steen H, and Reikerås O. Fibre optic bragg grating sensors: An alternative method to strain gauges for measuring deformation in bone. *Medical Engineering & Physics*. 2008; 30(1): 104-108.
75. Yu Q, and Zhou X. Pressure sensor based on the fiber-optic extrinsic fabry-perot interferometer. *Photonic Sensors*. 2011; 1(1): 72-83.
76. Liu X, Iordachita II, He X, Taylor RH, and Kang JU. Miniature fiber-optic force sensor based on low-coherence fabry-perot interferometry for vitreoretinal microsurgery. *Biomedical Optics Express*. 2012; 3(5): 1062-1076.
77. Bartelt H, Elsmann T, Habisreuther T, Schuster K, and Rothhardt M. Optical bragg grating sensor fibers for ultra-high temperature applications, *Conf Proc 5th Asia Pacific Optical Sensors Conference*. 2015.
78. Gao R, Jiang Y, Ding W, Wang Z, and Liu D. Filmed extrinsic fabry-perot interferometric sensors for the measurement of arbitrary refractive index of liquid. *Sensors and Actuators B: Chemical*. 2013; 177: 924-928.
79. Sante RD. Fibre optic sensors for structural health monitoring of aircraft composite structures: Recent advances and applications. *Sensors*. 2015; 15(8): 18666-18713.
80. Mihailov SJ. Fiber bragg grating sensors for harsh environments. *Sensors*. 2012; 12(2): 1898-1918.

81. Kanellos GT, Papaioannou G, Tsiokos D, Mitrogiannis C, Nianios G, and Pleros N. Two dimensional polymer-embedded quasi-distributed fbg pressure sensor for biomedical applications. *Optics Express*. 2010; 18(1): 179-186.
82. Kanellos GT, Tsiokos D, Pleros N, Papaioannou G, Childs P, and Pissadakis S. Enhanced durability fbg-based sensor pads for biomedical applications as human-machine interface surfaces, *Conf Proc International Workshop on Biophotonics*. 2011.
83. Al-Fakih EA, Osman NA, Adikan FR, Eshraghi A, and Jahanshahi P. Development and validation of fiber bragg grating sensing pad for interface pressure measurements within prosthetic sockets. *IEEE Sensors Journal*. 2015; 16(4): 965-974.
84. Al-Fakih E, Osman N, Eshraghi A, and Adikan F. The capability of fiber bragg grating sensors to measure amputees' trans-tibial stump/socket interface pressures. *Sensors*. 2013; 13(8): 10348-10357.
85. Zhang ZF, Tao XM, Zhang HP, and Zhu B. Soft fiber optic sensors for precision measurement of shear stress and pressure. *IEEE Sensors Journal*. 2013; 13(5): 1478-1482.
86. Donati M, Vitiello N, Rossi SD, Lenzi T, Crea S, Persichetti A, Giovacchini F, Koopman B, Podobnik J, Munih M, and Carrozza M. A flexible sensor technology for the distributed measurement of interaction pressure. *Sensors*. 2013; 13(1): 1021-1045.
87. Rossi SD, Lenzi T, Vitiello N, Donati M, Persichetti A, Giovacchini F, Vecchi F, and Carrozza MC. Development of an in-shoe pressure-sensitive device for gait analysis, *Conf Proc International Conference of the IEEE Engineering in Medicine and Biology Society, EMBC*. 2011; 5637-5640.
88. Missinne J, Bosman E, Hoe BV, Verplancke R, Steenberge GV, Kalathimekkad S, Daele PV, and Vanfleteren J. Two axis optoelectronic tactile shear stress sensor. *Sensors and Actuators A: Physical*. 2012; 186: 63-68.
89. Lincoln LS, Quigley M, Rohrer B, Salisbury C, and Wheeler J. An optical 3d force sensor for biomedical devices, *Conf Proc 4th IEEE RAS & EMBS International Conference on Biomedical Robotics and Biomechanics (BioRob)*. 2012; 1500-1505.
90. Cutkosky MR, Howe RD, and Provancher WR. *Force and tactile sensors*. Berlin, Heidelberg: Springer; 2008.
91. Yousef H, Boukallel M, and Althoefer K. Tactile sensing for dexterous in-hand manipulation in robotics—a review. *Sensors and Actuators A: Physical*. 2011; 167(2): 171-187.
92. Baars EC, and Geertzen JH. Literature review of the possible advantages of silicon liner socket use in trans-tibial prostheses. *Prosthetics and Orthotics International*. 2005; 29(1): 27-37.
93. Sengh DM, and Herr H. A variable-impedance prosthetic socket for a transtibial amputee designed from magnetic resonance imaging data. *Journal of Prosthetics and Orthotics*. 2013; 25(3): 129-137.
94. Ghoseiri K, and Safari MR. Prevalence of heat and perspiration discomfort inside prostheses: Literature review. *Journal of Rehabilitation Research and Development*. 2014; 51(6): 855-868.
95. T.Peery J, Ledoux WR, and Klute GK. Residual-limb skin temperature in transtibial sockets. *Journal of Rehabilitation Research & Development*. 2005; 42(2): 147-154.
96. Klute GK, Rowe GI, Mamishev AV, and Ledoux WR. The thermal conductivity of prosthetic sockets and liners. *Prosthetics and Orthotics International*. 2007; 31(3): 292-299.
97. Peery JT, Ledoux WR, and Klute GK. Residual-limb skin temperature in transtibial sockets. *Journal of Rehabilitation Research & Development*. 2005; 42(2): 147-154.
98. Huff EA, Ledoux WR, Berge JS, and Klute GK. Measuring residual limb skin temperatures at the skin-prosthesis interface. *JPO: Journal of Prosthetics and Orthotics*. 2008; 20(4): 170-173.
99. Caldwell R, and Fatone S. Technique for perforating a prosthetic liner to expel sweat. *Journal of Prosthetics and Orthotics*. 2017; 29(3): 145-147.
100. Bertels T, Kettwig T, and . IPot. Breathable liner for transradial prostheses, *Conf Proc Myoelectric Symposium*. 2011.
101. Wernke MM, Schroeder RM, Kelley CT, Denuene JA, and Colvin JM. Smarttemp prosthetic liner significantly reduces residual limb temperature and perspiration. *JPO: Journal of Prosthetics and Orthotics*. 2015; 27(4): 134-139.
102. Han Y, Liu F, L. Zhao, and Zhe J. An automatic and portable prosthetic cooling device with high cooling capacity based on phase change. *Applied Thermal Engineering*. 2016; 104: 243-248.
103. Ghoseiri K, Zheng YP, Leung AK, Rahgozar M, Aminian G, Lee TH, and Safari MR. Temperature measurement and control system for transtibial prostheses: Functional evaluation. *Assistive Technology*. 2018; 30(1): 16-23.
104. Han Y, Liu F, Dowd G, and Zhe J. A thermal management device for a lower-limb prosthesis. *Applied Thermal Engineering*. 2015; 82: 246-252.
105. Webber CM, and Davis BL. Design of a novel prosthetic socket: Assessment of the thermal performance. *Journal of Biomechanics*. 2015; 48(7): 1294-1299.
106. Zhe J and Han Y. Low-power method and device for cooling prosthetic limb socket based on phase change. *University of Akron. United States patent 9,814,607*. 2017.
107. King C. Vacuum assisted heat/perspiration removal system and limb volume management for prosthetic device. *United States patent 11/518,064*. 2007.
108. King C. Airflow regulation system for artificial limb and associated methods. *United States patent 8,475,537*. 2013.
109. Board WJ, Street GM, and Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International*. 2001; 25(3): 202-209.
110. Lilja M, Johansson S, and Öberg T. Relaxed versus activated stump muscles during casting for trans-tibial prostheses. *Prosthetics and Orthotics International*. 1999; 23(1): 13-20.
111. Fernie GR, Holliday PJ, and Lobb RJ. An instrument for monitoring stump oedema and shrinkage in amputees. *Prosthetics and Orthotics International*. 1978; 2(2): 69-72.
112. Commean PK, E.Smith K, Cheverud JM, and Vannier MW. Precision of surface measurements for below-knee residua. *Archives of Physical Medicine and Rehabilitation*. 1996; 77(5): 477-486.
113. Schreiner RE, and Sanders JE. A silhouetting shape sensor for the residual limb of a below-knee amputee. *IEEE Transactions on Rehabilitation Engineering*. 1995; 3(3): 242-253.
114. Krouskop TA, Dougherty D, Yalcinkaya MI, and Muilenberg A. Measuring the shape and volume of an above-knee stump. *Prosthetics and Orthotics International*. 1988; 12(3): 136-142.
115. Murka CPP. 3-d imaging of residual limbs using ultrasound. *Development*. 1997; 34(3): 269-278.
116. Smith KE, Commean PK, and Vannier MW. Residual-limb shape change: Three-dimensional ct scan measurement and depiction *in vivo*. *Radiology*. 1996; 200(3): 843-850.

117. Johansson S, and Öberg T. Accuracy and precision of volumetric determinations using two commercial cad systems for prosthetics: A technical note. *Journal of Rehabilitation Research and Development*. 1998; 35(1): 27.
118. Buis AW, Condon B, Brennan D, McHugh B, and Hadley D. Magnetic resonance imaging technology in transtibial socket research: A pilot study. *Journal of Rehabilitation Research & Development*. 2006; 43(7): 883-890.
119. Sanders JE, Rogers EL, and Abrahamson DC. Assessment of residual-limb volume change using bioimpedance. *Journal of Rehabilitation Research and Development*. 2007; 44(4): 525-536.
120. Sanders JE, and Cassisi DV. Mechanical performance of inflatable inserts used in limb prosthetics. *Journal of Rehabilitation Research & Development*. 2001; 38(4): 365-374.
121. Greenwald RM, Dean RC, and Board WJ. Volume management: Smart variable geometry socket (svgs) technology for lower-limb prostheses. *Journal of Prosthetics and Orthotics*. 2003; 15(3): 107-112.
122. Carrigan W, Nothnagle C, Savant P, Gao F, and Wijesundara MB. Pneumatic actuator inserts for interface pressure mapping and fit improvement in lower extremity prosthetics., *Conf Proc 6th IEEE International Conference on Biomedical Robotics and Biomechatronics (BioRob)*. 2016; 574-579.
123. Volder MD, and Reynaerts D. Pneumatic and hydraulic microactuators: A review. *Journal of Micromechanics and Microengineering*. 2010; 20(4): 043001.
124. Mercier M, Shirley C, Stafford S, Hitzke S, Byju A, Kevorkian C, Madigan M, and Philen M. Fluidic flexible matrix composites for volume management in prosthetic sockets, *Conf Proc ASME 2014 Conference on Smart Materials, Adaptive Structures and Intelligent Systems*. 2014; 1-7.
125. Phillips SL, Resnik L, and Latief GA. Use of a dynamic load strap in adjustable anatomical suspension for transradial amputations, *Conf Proc MyoElectric Symposium*. 2011.
126. Nakamura A, Abe N. Banner advertisement selecting method. NEC Corp. United States patent 6,591,248. 2003.
127. Wilson AB, Schuch CM, and Nitschke RO. A variable volume socket for below knee prostheses. *Clinical Prosthetics & Orthotics*. 1987; 11(1): 11-10.
128. Johnson A, Lee J, and Veatch B. Designing for affordability, application, and performance: The international transradial adjustable limb prosthesis. *PO: Journal of Prosthetics and Orthotics*. 2012; 24(2): 80-85.
129. Kahle JT, Klenow TD, and Highsmith MJ. Comparative effectiveness of an adjustable transfemoral prosthetic interface accommodating volume fluctuation: Case study. *Technology and Innovation*. 2016; 18(2-3): 175-183.
130. DeLisa JA. *Gait analysis in the science of rehabilitation*. Diane Publishing; 1998.
131. Koktas NS, Yalabik N, and Yavuzer G. Combining neural networks for gait classification, *Conf Proc Iberoamerican Congress on Pattern Recognition*. 2006; 381-388.
132. Morris SJ, and Paradiso JA. Shoe-integrated sensor system for wireless gait analysis and real-time feedback, *Conf Proc Second Joint 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society*. 2002; 2468-2469.
133. Smith BT, Coiro DJ, Finson R, Betz RR, and McCarthy J. Evaluation of force-sensing resistors for gait event detection to trigger electrical stimulation to improve walking in the child with cerebral palsy. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 2002; 10(1): 22-29.
134. Holmberg WS. An autonomous control system for a prosthetic foot ankle. *IFAC Proceedings Volumes*. 2006; 39(16): 856-861.
135. Williamson R, and Andrews BJ. Gait event detection for fcs using accelerometers and supervised machine learning. *IEEE Transactions on Rehabilitation Engineering*. 2009; 8(3): 312-319.
136. Chan HK, Zheng H, Wang H, Gawley R, Yang M, and Sterritt R. Feasibility study on iphone accelerometer for gait detection, *Conf Proc 5th International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops*. 2011; 184-187.
137. Aminian K, Najafi B, Büla C, Leyvraz PF, and Robert P. Spatio-temporal parameters of gait measured by an ambulatory system using miniature gyroscopes. *Journal of Biomechanics*. 2002; 35(5): 689-699.
138. Tong K, and Granat MH. A practical gait analysis system using gyroscopes. *Medical Engineering and Physics*. 1999; 21(2): 87-94.
139. Pappas IP, Popovic MR, Keller T, Dietz V, and Morari M. A reliable gait phase detection system. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*. 2001; 9(2): 113-125.
140. Erikson U, and Lemperg R. Roentgenological study of movements of the amputation stump within the prosthesis socket in below-knee amputees fitted with a ptb prosthesis. *Acta Orthopaedica Scandinavica*. 1969; 40(4): 520-526.
141. Grevsten S, and Erikson U. A roentgenological study of the stump—socket contact and skeletal displacement in the ptb-suction prosthesis. *Uppsala Journal of Medical Sciences*. 1975; 80(1): 49-57.
142. Lilja M, Johansson T, and Öberg T. Movement of the tibial end in a ptb prosthesis socket: A sagittal x-ray study of the ptb prosthesis. *Prosthetics and Orthotics International*. 1993; 17(1): 21-26.
143. Long IA. Normal shape-normal alignment (nsna) above-knee prosthesis. *Clinical Prosthetics & Orthotics*. 1985; 9(4): 9-14.
144. Mayfield GW, Scanlon JA, and Long I. A new look to and through the above-knee socket. *Orthop Trans*. 1977; 1(1): 95.
145. Sabolich J. Contoured adducted trachanteric-controlled alignment method (cat-cam): Introduction and basic principles. *Clin. Prosth. Orthos*. 1985; 9: 15-26.
146. Murray KD, and Convery P. The calibration of ultrasound transducers used to monitor motion of the residual femur within a trans-femoral socket during gait. *Prosthetics and Orthotics International*. 2000; 24(1): 55-62.
147. Ward S, Wiedemann L, Stinear C, Stinear J, and McDaid A. The influence of the re-link trainer on gait symmetry in healthy adults, *Conf Proc International Conference on Rehabilitation Robotics (ICORR)*. 2017; 276-282.
148. McDaid A, Tsoi YH, and Xie S. Mimo actuator force control of a parallel robot for ankle rehabilitation. *Interdisciplinary Mechatronics*. 2013; 163-208.
149. Kora K, Stinear J, and McDaid A. Design, analysis, and optimization of an acute stroke gait rehabilitation device. *Journal of Medical Devices*. 2017; 11(1): 014503.
150. Cutti A, Perego P, Fusca M, Sacchetti R, and Andreoni G. Assessment of lower limb prosthesis through wearable sensors and thermography. *Sensors*. 2014; 14(3): 5041-5055.
151. Levy SW. Skin problems of the leg amputee. *Prosthetics and Orthotics International*. 1980; 4(1): 37-44.
152. Rajbhandari SM, Sutton M, Davies C, Tesfaye S, and Ward JD. 'Sausage toe': A reliable sign of underlying osteomyelitis. *Diabetic Medicine*. 2000; 17(174-77):

153. Grayson ML, W.Gibbons G, Balogh K, Levin E, and Karchmer AW. Probing to bone in infected pedal ulcers: A clinical sign of underlying osteomyelitis in diabetic patients. *Jama*. 1995; 273(9): 721-723.
154. Croll SD, G.Nicholas G, Osborne MA, Wasser TE, and Jones S. Role of magnetic resonance imaging in the diagnosis of osteomyelitis in diabetic foot infections. *Journal of Vascular Surgery*. 1996; 24(2): 266-270.
155. Kaleta JL, Fleischli JW, and Reilly CH. The diagnosis of osteomyelitis in diabetes using erythrocyte sedimentation rate: A pilot study. *Journal of the American Podiatric Medical Association*. 2001; 91(9): 445-450.
156. Crerand S, Dolan M, Laing P, Bird M, L.Smith M, and Klenerman L. Diagnosis of osteomyelitis in neuropathic foot ulcers. *The Journal of Bone and Joint Surgery*. 1996; 78(1): 51-55.
157. Yuh WT, Corson JD, Baraniewski HM, Rezai K, Shamma AR, Kathol MH, Sato Y, El-Khoury GY, Hawes DR, and Platz CE. Osteomyelitis of the foot in diabetic patients: Evaluation with plain film, 99mTc-MDP bone scintigraphy, and MR imaging. *American Journal of Roentgenology*. 1989; 152(4): 795-800.
158. Henrot P, Stines J, Walter F, Martinet N, Paysant J, and Blum A. Imaging of the painful lower limb stump. *Radiographics*. 2000; 20(suppl 1): S219-S235.
159. Baumgartner R, and Langlotz M. Amputee stump radiology. *Prosthetics and Orthotics International*. 1980; 4(2): 97-100.
160. Boutin RD, Pathria MN, and Resnick D. Disorders in the stumps of amputee patients: MR imaging. *American Journal of Roentgenology*. 1998; 172(2): 497-501.
161. Croll SD, Nicholas GG, Osborne MA, Wasser TE, and Jones S. Role of magnetic resonance imaging in the diagnosis of osteomyelitis in diabetic foot infections. *Journal of Vascular Surgery*. 1996; 24(2): 266-270.
162. Marcus CD, Ladam-Marcus VJ, Leone J, Malgrange D, Bonnet-Gausserand FM, and Menanteau BP. MR imaging of osteomyelitis and neuropathic osteoarthropathy in the feet of diabetics. *Radiographics*. 1996; 16(6): 1337-1348.
163. Dutronc H, Gobet A, Dauchy FA, Klotz R, Cazanave C, Garcia G, Lafarie-Castet S, Fabre T, and Dupon M. Stump infections after major lower-limb amputation: A 10-year retrospective study. *Médecine et Maladies Infectieuses*. 2013; 43(11-12): 456-460.
164. Zuluaga AF, Galvis W, Jaimes F, and Vesga O. Lack of microbiological concordance between bone and non-bone specimens in chronic osteomyelitis: An observational study. *BMC Infectious Diseases*. 2002; 2(1): 8.
165. Khatri G, Wagner DK, and Sohnle PG. Effect of bone biopsy in guiding antimicrobial therapy for osteomyelitis complicating open wounds. *The American journal of the medical sciences*. 2001; 321(6): 361-371.
166. Marples RR, Downing DT, and Kligman AM. Control of free fatty acids in human surface lipids by *Corynebacterium acnes*. *Journal of Investigative Dermatology*. 1971; 56(2): 127-131.
167. Gupta S, and Loh KJ. Noncontact electrical permittivity mapping and pH-sensitive films for osseointegrated prosthesis and infection monitoring. *IEEE Transactions on Medical Imaging*. 2017; 36(11): 2193-2203.
168. Wang L, Gupta S, Loh KJ, and Koo HS. Distributed pressure sensing using carbon nanotube fabrics. *IEEE Sensors Journal*. 2016; 16(12): 4663-4664.
169. Carlson JD, Matthis W, and Toscano JR. Smart prosthetics based on magnetorheological fluids, *Conf Proc Industrial and Commercial Applications of Smart Structures Technologies*. 2001; 308-316.
170. Glaessgen E, and Stargel D. The digital twin paradigm for future NASA and US Air Force vehicles, *Conf Proc 53rd AIAA/ASME/ASCE/AHS/ASC Structures, Structural Dynamics and Materials Conference 20th AIAA/ASME/AHS Adaptive Structures Conference*. 2012; 1818.
171. L.Golbranson F, Wirta RW, Kuncir EJ, Lieber RL, and Oishi C. Volume changes occurring in postoperative below-knee residual limbs. *Journal of Rehabilitation Research and Development* 1988; 25(2): 11-18.